DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 26, 2014

Konica Minolta, Inc.
% Mr. Russell D. Munves
Storch, Amini & Munves, PC
140 East 45th Street, 25th Floor
NEW YORK NY 10017

Re: K141271
Trade/Device Name: AeroDR SYSTEM 2
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB, LLZ
Dated: August 8, 2014
Received: August 13, 2014

Dear Mr. Munves:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141271

Device Name
AeroDR SYSTEM 2

Indications for Use *(Describe)*

The AeroDR SYSTEM 2 is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen system in general-purpse diagnostic procedures.
The AeroDR SYSTEM 2 is not indicated for use in mammography, fluoroscopy, tomography and angiography applications.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

as required by 807.92

1. Company Identification

Konica Minolta, Inc.
No.1 Sakura-machi, Hino-shi, Tokyo 191-8511, Japan
Establishment Registration Number: 3004485675

2. Submitter's Name and Address

Shigeyuki Kojima
Manager of Quality Assurance Operations
Regulations and Standards Section, Quality Assurance Center
No. 1 Sakura-machi, Hino-shi, Tokyo 191-8511, Japan
Telephone: 81-42-589-8429
Fax: 81-42-589-8053

3. Date of Submission

May 9, 2014

4. Device Trade Name

AeroDR SYSTEM 2

5. Common Name

Digital Radiography

6. Classification

Class Ⅱ

7. Product Code

Primary Product Code 90MQB: (Solid State X-ray Imager)
Subsequent Product Code: 90LLZ (Picture archiving and communications system)

8. Corresponding regulation

21CFR 892.1680: Stationary x-ray system

9. Predicate Device

AeroDR SYSTEMS 510(k) number K102349, K113248, K120477, K130936

10. Description of Device

The AeroDR SYSTEM 2 is a digital imaging system to be used with diagnostic x-ray systems. A new AeroDR Detector (flat panel digital detector: hereafter P-51) and AeroDR Generator Interface Unit2 has been just added to AeroDR SYSTEMS (The predicate devices:K102349, K113248, K120477, K130936) to function together such as with Console CS-7 (operator console), AeroDR Interface Unit, AeroDR Interface Unit2, AeroDR Generator Interface Unit, AeroDR Access Point and AeroDR Battery Charger, AeroDR Battery Charger2 and perform fundamentally same as Aero DR SYSTEMS do in physical and performance characteristics such as in device design, material safety and physical properties. Therefore, images captured with the flat panel digital detector in the AeroDR SYSTEM 2 can be communicated to the operator console via wired connection or wireless, depend on user's choice. The AeroDR SYSTEM 2 is just developed to meet user's compact layout needs without changing fundamental functions of the predicate devices.

AeroDR SYSTEM 2 is only connected with X-ray devices which are regally marketed in the United States of America and are compatible with XGIF, UEC, XIF Board along with certain electronic requirement, Specific signal controls for hardware and software and accessories described in Operation manual and Installation manual which is also fulfilled how to compatibility test at the time of installation also. In addition, for the use of pediatric, X-ray control system for pediatric are required.

11. Indications for Use

The AeroDR SYSTEM2 is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in general-purpose diagnostic procedures. The AeroDR SYSTEM 2 is not indicated for use in mammography, fluoroscopy, tomography and angiography applications.

12. Substantial Equivalence to Predicate Device

Although the new AeroDR Detector (flat panel digital detector whose material has been changed) and AeroDR Generator Interface Unit2 has been designed in the AeroDR SYSTEM 2 (the proposed device) to be used with diagnostic x-ray systems and with AeroDR SYTEMS' components (the predicate device). AeroDR SYSTEM 2 had been evaluated substantial equivalencies to the predicate device by the following points:

The Indications for use of proposed device and predicate devices are identical.

As a part of new outer materials of the new panel (p-51) which intact of human skin has been evaluated with the latest EN ISO 10993-1 and assured the safety as same as the predicate devices has. In addition, Inner material change for a righter weight, battery change for an attainment of its longer time/duration and IPX6 waterproof has been designed for the P-51 panel. So the electrical safety (AAMI / ANSI ES60601-1:2005/(R) 2012 and C1:2009/(R) 2012 and A2:2010/(R) 2012) and the electromagnetic compatibility testing (IEC 60601-1-2) had been conducted and assured as the predicate devices as well. In technical characteristics, hardware and software of the new panel and an accessory's verification and validation, (for the Wireless function, Radio Frequency Wireless Technology in Medical Device Guidance issued on August 14, 2013 was referred), Risk management based on ISO14971 had been completed without problem, performance testing (Bench Testing) including Non clinical and clinical testing referring to the FDA Guidance of the Submission of 510K (k')s for Solid State X-ray imaging Device had been concluded and showed equivalent evaluation outcome, which has supported a fact that no impacts in technological characteristic such as design, material chemical composition energy sauce and other factors of the proposed device were recognized. The all evaluation results can assure that there are no safety and effectiveness and performance issue or no differences were found in further than the predicate devices have which have been regally marketed in the United Sates. Therefore, we confirmed that AeroDR SYSTEM 2 has the same substantial equivalency to the predicate device, AeroDR SYSTEMs have.

13. Conclusion

Comprehensively, we judged that the AeroDR SYSTEM 2 has fundamentally the same technological characteristics as the predicate devices have. Therefore, this 510(k) has been able to conclude as substantial equivalence as the predicate devices.